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REMARKS

This invention provides for a transdermal therapy system (TTS) which comprises an active agent depot and a matrix wherein at least either the active agent depot or the matrix comprises a support material which consists of paper. This invention further provides for a process for preparing the inventive TTS. The inventive TTS exhibits improved processing and delivery properties (see Example I and Example 2).

It is believed that no fee is required for the consideration of this Amendment. If it is determined that a fee is due, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment to Deposit Account 50-0320.

Claims 7 to 14 stand rejected under 35 USC §103(a) as being unpatentable over Hoffman, U.S. Patent 5,820,876 in view of Nichols U.S. Patent 4,804,541. Applicants have respectfully disagreed arguing that Hoffman taken with Nichols in any fair combination do not suggest a TTS which comprises an active agent depot or a matrix that comprises a support material which consists of paper. Accordingly, it was urged that the rejection does not establish a *prima facie* case of obviousness and reconsideration and withdrawal of the rejection were requested.

In response to the rejection, Applicants respectfully argued that Nichols did not correct the deficiencies found with Hoffman, which does not disclose a TTS comprising a support material consisting of paper, because the cellulose-based derivatives described in Nichols are absorbent materials, such as fibrous batts or cotton fibers. These absorbent materials, it was argued, would not add structural rigidity to a TTS since these materials are flimsy. Paper No. 21 at 6-7.

In addressing this argument in the Examiner states:

> Applicant argues that the paper of Nichols would create a non-rigid TTS, yet the rigidity of the TTS has not been claims in the instant application. The claims merely recite that the support material consists of paper. Applicant qualifies this limitation in the specification by disclosing the advantages of absorbent paper as a support medium. Nichols discloses a TTS with a support medium of absorbent paper. The fact that Hoffman does not disclose the presence of paper is irrelevant since Hoffman is the reference being modified. If applicant would like to claim the rigidity of the TTS along with other more defining features of the paper support material, applicant is more than welcome. The limitations of course should find support in the specification, and might require a further search.

Paper No. 24 at 2. Applicants would like to address these issues as follows:

Applicants respectfully urge that the terms "paper support" and "the support material consists of paper" excludes the absorbent paper disclosed in Nichols and inherently imply that the paper used in the TTS must exhibit sufficient rigidity to function as a support. The term "paper support" by definition implies that the paper must be sufficiently rigid to permit the system to function as a TTS. Thus, one skilled in the art would discard a material such as cotton fibers for not providing sufficient rigidity to the TTS. Moreover, it should be emphasized that the claims state that "the support material consists of paper," thereby excludes the presence of other materials in the support material in addition to paper. Moreover, Applicants respectfully urge that absent the modifier "absorbent" the term "paper" by itself inherently would be a property of paper since paper comprises lignin which, according to a document of Applied Paper Technology, Inc. (www.paperelements.com) (copy enclosed) "is largely responsible for the strength and rigidity of the paper."

Thus, in view of the foregoing, it is urged that the rejection does not establish a *prima facie* case of obviousness and withdrawal of this rejection is requested.

Favorable action is earnestly solicited.

Respectfully submitted,

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GLOSARY OF PAPER TERMS & INFORMATION

Acid Free • Papers that are without acid in the pulp and have a pH of 7.0 to 9.0 at the time of manufacture.
Acid Migration • Occurs when paper comes in contact with acidic material or is exposed to atmospheric pollution.
Archival • Paper that is not only acid free but also lignin and sulpher free.
Buffering • Paper is neutralized by adding an alkaline such as calcium carbonate t the paper pulp to protect from the environment.
Cellulose • The cell wall of plants. Cotton in its raw state contains about 91% cellulose and is the purest form of natural cellulose.
Chin Colle • A paper collage process in which thin sheets of paper are laminated together by the pressure of an etching press and glue.
Chiri • A Japanese term for the bark from the mulberry tree.
Cold Pressed • Paper surface with a slight to rough texture is created by pressing the sheets between various cold cylinders.
Daphne • A thin bast fiber native to Nepal.
Deckle Edge • The feathered outer edge that occurs as a sheet of fine quality handmade paper is formed when the deckle is removed from the mould.
Esparto • A tough grass that grows without cultivation in North Africa.
GSM • The gram weight of one square meter of paper.
Grain Direction • The direction in which fibers lie in a finished sheet of paper. Determined by the movement of the paper as it travels through the paper machine c on the papermakers mould.
High Alpha Cellulose • A very pure form of wood pulp which is considered to hav the same longevity as cotton or other plant fibers.
Hollander Beater • Machine that crushes & beats plant fiber or rags to a pulp.
Hot Pressed • Pressing the sheets of paper between hot metal cylinders creates a smooth surface.
Kozo • The long rough bark fiber from the mulberry tree that produces strong absorbent sheets of paper.
Lignin • A component of the cell walls of plants. Lignin is largely responsible for the strength and rigidity of paper but its presence in paper is also believed to contribute chemical degradation.
pH • In chemistry, pH is a measure of acidity or alkalinity. Scale runs from 0 to 14 where 7 is pH neutral: numbers below 7 indicate acidity, numbers above 7 indicate increasing alkalinity.
Recycled Paper • Paper made from post consumer waste. Used paper is cooked chemicals, de-inked and reduced to pulp then made into new paper.
Rice Paper • A common misnomer used to describe Oriental paper. Oriental pape: is not made from rice...
Size • The process of adding gelatin on the sheets of paper or starch in the paper pulp to provide a barrier from moisture.
Sulphite • Pulp is produced from the wood of coniferous trees. "Sulphite" has become a generic term and is still accurately used to describe any paper made from wood, in distinction from papers made from cotton.
Unryu • In Japanese "cloud dragon paper", containing stands of fiber that add contrast and texture.
Washi • Japanese Wa, meaning "Japan", and Shi, meaning "paper".

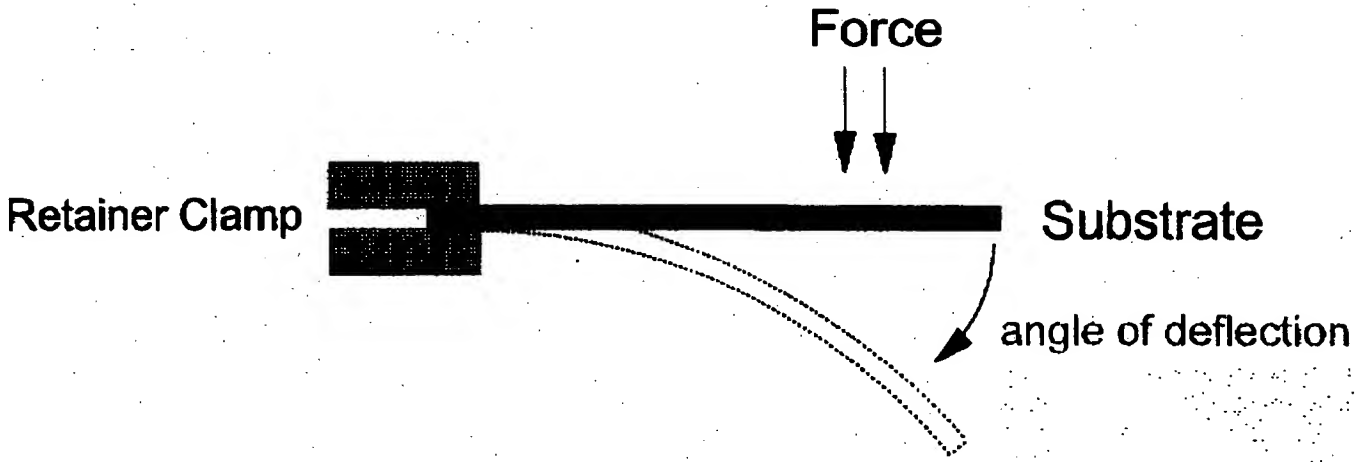
Bending Stiffness

Bending stiffness is an expression of the rigidity of paper or paperboard. This property is related to the modulus of elasticity of the product and its thickness. There are several instruments in use in the industry that measure stiffness, and they all bend the product to measure stiffness. There are 2-point bending instruments and 4-point bending instruments. Solid fiber board and small fluted combined board (to be used in folding cartons) is typically measured with 2-point bending instruments.

Commonly used instruments include Taber, Gurley, and L&W. In the USA Taber Stiffness is the most common stiffness measurement. In Europe L&W is most common.

When stiffness is reported it is important to know how much bending took place. The typical Taber stiffness t st for solid fiber board uses a 15 deg bending. Small flute combined board cannot be bent to 15 deg without damaging the product, so it is necessary to bend to a lesser degree. The Taber stiffness tester can only be set to reach an end-point at 15 deg or at 7.5 deg of bending, and sometimes the product is damaged at 7.5 deg. We test small flute product at 7.5 deg using the Taber instrument, and we discard results when we recognize that th sample was damaged

The L&W instrument can be set to reach an end-point at various degrees of bending, therefore we use 5 deg bending for small flute products. This assures that the sample is not damaged, improving the reliability of th test results. Also, in Europe, 5 deg bending is fairly common, when using the L&W instrument.



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